UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

JONATHAN A. BLOOM, Plaintiff, v. ALEX AZAR, Secretary, United States Department of Health and Human Services,[1] Defendant.	)	Case No. 5:16-cv-121

OPINION AND ORDER
(Docs. 34, 35)

Plaintiff Dr. Jonathan A. Bloom brings this action under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A), seeking judicial review of three decisions by the Medicare Appeals Council ("MAC") denying his requests for Medicare payment of claims relating to a continuous glucose monitor, which he asserts is the "standard of care" for individuals who, like himself, suffer from "brittle" diabetes. (*See* Doc. 21 (Amended Complaint); *see also* Doc. 21-1 (unfavorable MAC decision dated February 24, 2016 in No. M-15-4332); Doc. 21-2 (unfavorable MAC decision dated November 13, 2015 in No. M-15-1505); Doc. 21-8 (unfavorable MAC decision dated January 27, 2017 in No. M-16-10554).) Previously in this case, the court denied the Secretary's motion to remand under the sixth sentence of § 405(g). (Doc. 20.)

[1] Under Fed. R. Civ. P. 25(d), Secretary Azar, in his official capacity, is substituted as the named defendant.

The Secretary has filed the administrative records for each of the three MAC decisions at issue. (*See* Docs. 18, 27.)[2] Currently pending are Dr. Bloom's motion to reverse (Doc. 34) and the Secretary's motion to affirm (Doc. 35), both filed in accordance with Local Rule 9. The court held a hearing on those motions on December 19, 2017. (*See* Doc. 48 (hearing transcript).)

Background

Drawing largely on Dr. Bloom's testimony, the court begins with some background about Dr. Bloom and how he manages his diabetes. Additional facts and procedural history are set forth below.

Dr. Bloom was born in 1944 and diagnosed with Type 1 diabetes[3] in 1974. (*See* AR1 at 282, 377.) His diabetes is "brittle," (AR1 at 282, 377), meaning that he experiences "marked fluctuations in blood glucose [sugar] concentrations that are difficult to control." *Stedman's Medical Dictionary* 243150 (2014). Although he was able to recognize hypoglycemia (low blood sugar) when he was younger, Dr. Bloom currently has "hypoglycemic unawareness." (AR1 at 282; *id.* at 380 ("I just don't recognize hypoglycemia. . . . [W]hen I was younger . . . I recognized it much more quickly.").)

Dr. Bloom has used various technologies to help manage and control his diabetes. He testified that in 1978 he became one of the first people in America to have a home glucose monitoring system. (AR1 at 380.) That technology requires a "finger prick" (AR1 at 384) to

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[2] Because there are three administrative records in this case, the court adopts Dr. Bloom's convention and distinguishes the records by citing them as "AR1" (for the record associated with No. M-15-4332), "AR2" (for the record associated with No. M-15-1505), and "AR3" (for the record associated with No. M-16-10554).

[3] Type 1 diabetes (also known as juvenile-onset diabetes) is "a condition characterized by high blood glucose levels caused by a total lack of insulin." *Stedman's Medical Dictionary* 243520 (2014). The condition occurs "when the body's immune system attacks the insulin-producing beta cells in the pancreas and destroys them." *Id.*

obtain a sample of blood to be applied to a test strip that is read by a blood glucose meter. Dr. Bloom has continued checking his blood sugars that way for decades, progressing through "all of the generations" of home glucose monitors. (AR1 at 380.) The "finger prick" glucose monitoring technology measures glucose at a single point in time; Dr. Bloom testified that he checks his blood glucose this way between 10 and 15 times each day. (*See* AR1 at 380.) He is not able to check his blood glucose this way while he is busy at work or while he is asleep. (AR1 at 381.)

Dr. Bloom was prescribed a Medtronic-Minimed "continuous" glucose monitor ("CGM") in 2006. (AR1 at 282, 381.) The CGM system that he uses includes a sensor, a transmitter, and a monitor. (*See* AR1 at 43, 379, 381.) The sensor is injected with a needle, and after the needle is removed the sensor is connected to the transmitter. (AR1 at 379.) The transmitter sends the sensor's readings to the monitor and also to an insulin pump, which is integrated with Dr. Bloom's CGM system. (*See* AR1 at 379–80.)

The sensors have a limited lifespan and are not reusable. Earlier models of the sensors lasted for three days, and the current sensors work for six days. (AR1 at 391.) The monitor displays the data collected from the sensor and has hypoglycemic alarms that allow Dr. Bloom to "detect, check and treat impending hypoglycemia, particularly when it occurs during sleep." (AR1 at 43–44.) When he is wearing his CGM system, Dr. Bloom receives "reliable alarms and is able to react appropriately." (AR1 at 47.)

In addition to the CGM system, Dr. Bloom continues to check his blood sugar using a finger prick, test strip, and a blood glucose meter. (AR1 at 380.) He describes the test strips as "effective." (AR1 at 380.) According to Dr. Bloom, even when using a CGM, "you still need to

monitor your blood sugar and prick your finger," but the CGM "may help you spot patterns or trends easier." (AR1 at 385.)

Dr. Richard Pratley at the Vermont Regional Diabetes Center has treated Dr. Bloom in recent years. (*See* AR1 at 45–46.) According to Dr. Pratley, Dr. Bloom "has had virtually no significant microvascular complications, due to his scrupulous glycemic control over the years." (*Id.* at 43.) Still, prior to acquiring his CGM system, Dr. Bloom experienced two hypoglycemic events resulting in loss of consciousness and requiring medical intervention. (*See* AR1 at 282 (recounting events in 1984 and 2005).) Dr. Pratley describes these past episodes as "life threatening." (AR1 at 286.)

Since he began using the CGM, Dr. Bloom reports that he has experienced only one incident of undetected hypoglycemia, when he fell asleep on a 2008 transcontinental flight with his earphones in and did not hear the monitor go off. (AR1 at 282, 381.) According to Dr. Pratley, Dr. Bloom's use of a CGM system "has markedly improved his management, quality of life and overall safety." (AR1 at 44.) Also according to Dr. Pratley, the CGM system "has provided a clinically significant benefit in terms of [Dr. Bloom's] diabetes management and especially with respect to the avoidance of hypoglycemia." (*Id.*) Dr. Pratley's opinion is that "it is essential that [Dr. Bloom] continue on insulin pump therapy with continuous glucose monitoring." (AR1 at 286–87.)

MAC Decisions

"The Medicare Act, 42 U.S.C. § 1395 et seq., establishes the federal program of health insurance for the elderly." *Exec. Dir. of Office of Vt. Health Access ex rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 439 (D. Vt. 2010). Part "B" of the program generally covers, among other things, "medical and other health care services." 42 U.S.C. § 1395k(a)(2)(B). "Medical and

other health services" includes "durable medical equipment." *Id.* § 1395x(s)(6). The statutory definition of "durable medical equipment" ("DME") is a list of certain equipment that is included and certain equipment that is excluded. *Id.* § 1395x(n). DME is defined to include "blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations)." *Id.* Generally excluded from coverage are "any expenses incurred for items or services . . . [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A).

Medicare program administrators make coverage determinations, and the law provides a multi-step administrative process for a beneficiary to challenge denials, progressing from the "initial determinations" (which include "redeterminations"), to "reconsideration," to a hearing before an administrative law judge ("ALJ"), and finally to review by the Medicare Appeals Council ("MAC"). *See* 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904. After completion of the administrative review process, judicial review is available. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.904.

It is undisputed that Dr. Bloom is a Medicare beneficiary and that this action arises under Medicare Part B. (Doc. 21 ¶¶ 17, 21; Doc. 26 ¶¶ 17, 21.) In this case, Dr. Bloom seeks judicial review of three unfavorable MAC decisions issued after his requests for coverage relating to his CGM progressed through the earlier stages of the administrative appeals process. The court briefly summarizes each of the three unfavorable MAC decisions here, with additional details recited as necessary below.

I. Unfavorable MAC Decision Dated November 13, 2015 in No. M-15-1505

In its November 13, 2015 decision, the MAC, on its own motion, reviewed and reversed a June 23, 2015 favorable decision issued by ALJ Bennett Engelman. (AR2 at 20–28.) The ALJ had conducted a hearing (AR2 at 4–11), and issued a decision (AR2 at 38–46) concluding that disposable sensors for Dr. Bloom's CGM system provided on August 6, 2014 were covered by Medicare, and that Dr. Bloom was entitled to payment based on the billed amount of $473. The ALJ discussed National Coverage Determination (NCD) 280.1, NCD 40.2, Local Coverage Determination (LCD) L11530, and Local Coverage Article (LCA) A33614. (AR2 at 45.) The ALJ noted that LCA A33614 states that CGMs are considered "precautionary and therefore non-covered under the DME [durable medical equipment] benefit." (*Id.*) The ALJ found "extensive" justification in the record for departing from LCA A33614, noting that Dr. Bloom "suffers from a rare and dangerous combination of diabetic complications which may place his life in jeopardy without the use of a continuous blood glucose monitor and its required sensors." (*Id.* at 45–46.) According to the ALJ, "continuous blood glucose sensors are not 'precautionary' as the coverage article claims; these sensors are a reasonable and necessary element of his medical care." (*Id.* at 46.)

The MAC reversed the ALJ's favorable determination, concluding that Medicare does not cover the sensors "because they do not fall within the statutory Durable Medical Equipment (DME) benefit category." (AR2 at 21.) The MAC concluded that CGM's are "precautionary" items, reasoning that "since the CGM does not substitute for the existing means of controlling insulin usage, or measure blood glucose directly, we conclude that it merely provides an added precaution and does not itself serve a primary medical purpose." (AR2 at 27.)

II. Unfavorable MAC Decision Dated February 24, 2016 in No. M-15-4332

In its February 24, 2016 decision, the MAC reviewed and adopted two separate unfavorable ALJ decisions: one dated March 31, 2015 and one dated April 8, 2015. (AR1 at 3–12.) In the March 31, 2015 decision, ALJ Charles Wm. Dorman, after a hearing (AR1 at 402–06), concluded that Dr. Bloom's disposable CGM sensors and the external transmitter for use with the CGM system are not covered by Medicare. (AR1 at 84.) ALJ Dorman followed LCA A33614 and concluded that Dr. Bloom's CGM system is not "durable medical equipment." (*See* AR1 at 85.) In the April 8, 2015 decision, ALJ Pere J. Jarobe, after a hearing (AR1 at 376–95), concluded that "[t]here can be no coverage for the disposable Sensors for use with continuous glucose monitors . . . because they are explicitly excluded from Medicare coverage by the relevant LCA as precautionary." (AR1 at 57.)

The total cost of the sensors and transmitter for which ALJs Dorman and Jarobe denied coverage was $1,976. (AR1 at 168, 314, 316.) In adopting both of the unfavorable ALJ decisions, the MAC concluded that "CGMs do not fall within the DME benefit category, and, therefore, supplies for such devices are also non-covered." (AR1 at 12.)

III. Unfavorable MAC Decision Dated January 27, 2017 in No. M-16-10554

In its January 27, 2017 decision, the MAC reviewed an August 23, 2016 unfavorable decision issued by ALJ Steven C. Goga. (AR3 at 3.) The ALJ had conducted a hearing (AR3 at 809–26), and issued a decision (AR3 at 53–74) concluding, among other things, that Dr. Bloom's CGM sensors "are excluded from coverage under the Medicare Durable Medical Equipment (DME) benefit." (AR3 at 54.) The cost of the sensors for which ALJ Goga denied coverage was $1,419. (AR3 at 317.) The MAC agreed with the ALJ that Medicare does not

cover the sensors, reasoning that "the CGM system in this case is not DME and therefore the supplies are not covered as supplies for DME." (AR3 at 9.)

Standard of Review

Under 42 U.S.C. § 1395ff(b)(1)(A), an individual is entitled to judicial review of the final decision of the Secretary of Health and Human Services as provided in 42 U.S.C. § 405(g). Under § 405(g), the court reviews the administrative record to determine if there is "substantial evidence" to support the agency's decision. The court may set aside the agency's determination if it is not supported by substantial evidence or if it is based on a legal error. *See Keefe ex rel. Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995).

The court's review of legal conclusions is de novo. *Id.*; *see also Carey*, 698 F. Supp. 2d at 439 (court is not bound by Secretary's conclusions or interpretations of law, or to application of incorrect legal standard). On the other hand, review of factual findings is deferential because it is limited to whether the findings are supported by substantial evidence. "Substantial evidence is 'more than a mere scintilla' and 'means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Lesterhuis v. Colvin*, 805 F.3d 83, 87 (2d Cir. 2015) (per curiam) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)) (referring to a final decision of the Commissioner of Social Security). "In determining whether substantial evidence exists the reviewing court analyzes the record as a whole." *Carey*, 698 F. Supp. 2d at 439 (quoting *State of N.Y. ex rel. Bodnar v. Sec'y of Health & Human Servs.*, 903 F.2d 122, 126 (2d Cir. 1990)). The remedial purpose of the Medicare Act requires that it be construed broadly. *Carey*, 698 F. Supp. 2d at 440. Still, the claimant bears the burden of proving his or her entitlement to Medicare coverage. *Keefe*, 71 F.3d at 1062.

The court rejects Dr. Bloom's suggestion that review is governed by the provisions of the Administrative Procedure Act, and specifically 5 U.S.C. § 706. As the Second Circuit has observed, "Section 1395ff(b) specifies 42 U.S.C. § 405(g) as the sole avenue for judicial review for all claim[s] arising under the Medicare Act." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78 (2d Cir. 2006) (alteration in original; internal quotation marks omitted). The court conducts its review in this case under § 405(g).

Analysis

The parties have presented two main issues in their competing motions. First, the Secretary challenges the court's jurisdiction to review two of the three unfavorable MAC decisions for failure to meet the requisite amount in controversy. Second, the parties disagree about whether a CGM qualifies as DME. The court begins with the jurisdictional question.

I. Jurisdiction—Amount in Controversy

The Secretary argues that Dr. Bloom's challenges to the November 13, 2015 and January 27, 2017 MAC decisions (Nos. M-15-1505 and M-16-10554, respectively) should be dismissed for lack of jurisdiction because the amount in controversy is not met. (Doc. 35 at 15.) Dr. Bloom maintains that the court has subject-matter jurisdiction to review both of those decisions under 42 U.S.C. § 1395ff(b)(1)(E) and under 28 U.S.C. § 1367(a). (Doc. 38 at 7–13.)

A. Section 1395ff(b)(1)(E); Aggregation

A MAC decision on coverage under Medicare Part B is subject to judicial review if the amount in controversy is at least $1,000, adjusted for inflation. *See* 42 U.S.C. § 1395ff(b)(1)(E)(i), (iii); 42 C.F.R. § 405.1006(c). For calendar year 2015, the inflation-adjusted amount in controversy for judicial review was $1,460; and for calendar year 2017, the inflation-adjusted amount in controversy for judicial review was $1,560. *Medicare Program;*

Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2017, 81 Fed. Reg. 65,651-03, 2016 WL 5235087 (Sept. 23, 2016) (table lists threshold amounts). The claim at issue in the 2015 MAC decision was for $473, and the claim at issue in the 2017 MAC decision was for $1,419.

Dr. Bloom does not dispute that those sums are each lower than the inflation-adjusted amounts in controversy for the respective calendar years. Instead, he asserts that, under § 1395ff(b)(1)(E), the court can aggregate all of his claims. He argues that § 1395ff(b)(1)(E)(i) refers to judicial review being available "to the individual," such that the amount in controversy necessary for judicial review depends on whether the "individual" meets that sum, rather than whether any particular "claim" does. (*See* Doc. 38 at 8.) Dr. Bloom also contends that he asked for extensions of time in No. M-15-1505 specifically so that he could meet the amount in controversy.

> The relevant statutory language regarding "amounts in controversy" is as follows:
>
> (i) In general
>
> A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.
>
> (ii) Aggregation of claims
>
> In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve—
>
> (I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or
>
> (II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

42 U.S.C. § 1395ff(b)(1)(E). When interpreting a statute, the court begins with the text of the provision "to determine whether the language at issue has a plain and unambiguous meaning."

United States v. Epskamp, 832 F.3d 154, 162 (2d Cir. 2016) (quoting *Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 108 (2d Cir. 2012)). "A particular statute's plain meaning can best be understood by looking to the statutory scheme as a whole and placing the particular provision within the context of that statute." *Id.* (internal quotation marks omitted).

Here, Dr. Bloom urges that § 1395ff(b)(1)(E) permits the court to draw a distinction between the rules for aggregation at the administrative level and for aggregation at the judicial level. (Doc. 38 at 8.) The basis for that purported distinction is that § 1395ff(b)(1)(E)(i) refers to the availability of judicial review "to the individual" rather than on each "claim." The statutory language supplies no basis for drawing the distinction that Dr. Bloom advocates, however, since almost the same reference to the availability of review "to an individual" appears in § 1395ff(b)(1)(E)(i) regarding *administrative* hearings. If this language operated as Dr. Bloom argues, then § 1395ff(b)(1)(E)(ii) would be superfluous—all claims brought by any individual would be aggregated automatically at all levels.

Dr. Bloom is correct insofar as he observes that § 1395ff(b)(1)(E) is silent about aggregation of claims at the district court level. That provision speaks only to aggregation by "the *Secretary*" (not the courts). 42 U.S.C. § 1395ff(b)(1)(E)(ii) (emphasis added). But in the court's view, the lack of any mention of aggregation at the district court level suggests that Congress did *not* intend for the courts to be aggregating claims to meet the amount-in-controversy requirement of § 1395ff(b)(1)(E).

At least one other court addressing this issue has reached a similar conclusion. In *Epstein v. Burwell*, the court held that "[i]n order for multiple claims to be aggregated pursuant to these provisions [section 1395ff(b)(1)(E)(ii) and 42 C.F.R. § 405.1006], appellants must expressly request aggregation before the ALJ, and the ALJ must determine that other aggregation criteria

have been satisfied." No. CV 13-8728-GHK (CWx), 2014 WL 12591476, at *4 (C.D. Cal. Aug. 5, 2014). The *Epstein* court explicitly rejected the suggestion that the regulations permit aggregation for the first time in the district court. *Id.* at *5. The court reasoned that allowing aggregation for the first time in the district court would render the administrative aggregation criteria "a practical nullity," since under that interpretation a claimant "would undoubtedly opt to wait to aggregate at the judicial review stage, when . . . there would be no aggregation prerequisites whatsoever." *Id.* The court adopted the Secretary's view "that the Medicare regulations require that claims be aggregated *during the administrative process*." *Id.* (emphasis added). The court finds the *Epstein* court's analysis persuasive.

The authorities that Dr. Bloom cites do not compel a contrary result. The Federal Rules of Civil Procedure do speak to the "joinder of claims." *See* Fed. R. Civ. P. 18(a) ("A party asserting a claim, counterclaim, crossclaim, or third-party claim may join, as independent or alternative claims, as many claims as it has against an opposing party."). And in cases where 28 U.S.C. § 1332 (the diversity statute) establishes the amount in controversy for federal jurisdiction, "a plaintiff is permitted to aggregate claims in order to satisfy the amount in controversy requirement," with aggregation governed by Rule 18. *Wolde-Meskel v. Vocational Instruction Project Cmty. Servs., Inc.*, 166 F.3d 59, 62 (2d Cir. 1999).

But the reason that aggregation is allowed for the purposes of the diversity statute's amount in controversy is that the statute "confers jurisdiction over 'civil actions' rather than specific claims alleged in a complaint." *Id.* The amount-in-controversy requirement in this case, however, does not appear in the diversity statute; it appears in § 1395ff(b)(1)(E). Unlike the diversity statute, § 1395ff(b)(1)(E) does not confer jurisdiction over "civil actions." Absent a similar statutory basis on which to allow aggregation, Rule 18 cannot itself confer jurisdiction.

See Fed. R. Civ. P. 82 ("These rules do not extend or limit the jurisdiction of the district courts . . . .").

For this reason, Dr. Bloom's reliance on *Snyder v. Harris*, 394 U.S. 332 (1969), is misplaced. The Supreme Court in that case did state that "[a]ggregation has been permitted . . . in cases in which a single plaintiff seeks to aggregate two or more of his own claims against a single defendant." *Id.* at 335. But that statement was in the context of aggregation to satisfy the jurisdictional amount requirement in the diversity statute, not the requirement in § 1395ff(b)(1)(E).

Neither is Dr. Bloom's position on the aggregation issue supported by *Pavano v. Shalala*, 95 F.3d 147 (2d Cir. 1996). In *Pavano*, the Second Circuit stated that "[d]enial of relief by the Appeals Council is a final decision of the Secretary, which may be appealed to the district court (if the *aggregate* amount in controversy is $1000 or more)." *Id.* at 150 (emphasis added). But nothing in *Pavano* suggests that courts can do the aggregating in the first instance. The logical reading of the *Pavano* court's statement is that the court recognized that some decisions might arrive at the district court having already been aggregated at the administrative level.

Finally, Dr. Bloom argues that he actually did obtain aggregation at the administrative level. After the MAC's unfavorable 2015 decision, he invoked 42 C.F.R. § 405.1134 in two requests for extensions of time to file an action in federal district court. (AR2 at 14–15 (December 31, 2015 request); AR2 at 7–8 (March 3, 2016 request).) In both requests, Dr. Bloom indicated, among other things, that he had filed other appeals with the MAC for the same services for additional dates of services, and that the additional appeals needed to be consolidated in order to meet the federal amount-in-controversy requirement. Dr. Bloom also

represented that his counsel needed additional time to prepare a federal court action. The MAC granted both requests for extensions. (AR2 at 11, 1.)

The court does not perceive the MAC's grants of extensions to be grants of aggregation requests. Nothing in either grant of extension suggests that the MAC was aggregating any claims. The MAC simply stated that the requests for extensions were granted under 42 C.F.R. § 405.1134. (AR2 at 11, 1.) There is no indication that the MAC was granting extensions because it was aggregating claims rather than because it was persuaded by Dr. Bloom's other assertions for good cause, including his representation that counsel required additional time to prepare. Moreover, it is doubtful that the MAC would have granted an aggregation request raised for the first time with that body. *See* 42 C.F.R. § 405.1006(e) (claims may be aggregated "for an ALJ hearing"; no mention of aggregation at MAC level of review).

B. Section 1367; Supplemental Jurisdiction

Apart from his argument under § 1395ff(b)(1)(E), Dr. Bloom maintains that the court has supplemental jurisdiction to review the 2015 and 2017 MAC decisions under 28 U.S.C. § 1367 (supplemental jurisdiction). (*See* Doc. 38 at 9.) Noting that § 1367 generally applies "in any civil action of which the district courts have original jurisdiction," the Secretary asserts that the court does not have original jurisdiction in this case. (Doc. 40 at 3.)

The court rejects the Secretary's suggestion that the court lacks original jurisdiction. The court agrees with the Secretary that the court's jurisdiction in this case is not derived from 28 U.S.C. § 1331 (the federal question statute). But that does not mean that there is no basis for original jurisdiction in this case. Section 1331 is not the only basis on which a court might exercise original jurisdiction. To the contrary, "the Social Security Act—to the exclusion of federal question jurisdiction under 28 U.S.C. § 1331—provides the sole authority for exercising

federal jurisdiction over Medicare Part B disputes." *Abbey v. Sullivan*, 978 F.2d 37, 41 (2d Cir. 1992). Jurisdiction in this case derives from the Medicare Act. *See id.* at 43 (discussing "Jurisdiction Under the Medicare Act"). And, at least with respect to the MAC's 2016 decision, the district court has original (as opposed to appellate) jurisdiction under the Medicare Act because judicial review of the Secretary's decisions begins in the district court.

But because jurisdiction in this case derives from the Medicare Act, the aggregation rules of the Medicare Act apply. Dr. Bloom cannot use § 1367 to avoid those aggregation rules. *Cf. Esmilla v. Cosmopolitan Club*, No. 09 Civ. 10169(DF), 2011 WL 814007, at *5 (S.D.N.Y. Mar. 3, 2011) ("Section 1367 does not provide a mechanism for avoiding the jurisdictional limit, and related aggregation rules, of Section 1332."). For the above reasons, the court concludes that it lacks jurisdiction to review the MAC's decisions dated November 13, 2015 (No. M-15-1505) and January 27, 2017 (No. M-16-10554). The court therefore confines its review to the MAC's unfavorable decision dated February 24, 2016 in No. M-15-4332.

II. Durable Medical Equipment—Primary and Customary Use

As noted above, the basis for the MAC's unfavorable 2016 decision was its conclusion that "CGMs do not fall within the DME benefit category, and, therefore, supplies for such devices are also non-covered." (AR1 at 12.) Dr. Bloom argues that the MAC's decision is unsupported by substantial evidence and is contrary to law. (Doc. 34 at 14.) The Secretary maintains that the MAC "reasonably interpreted the Medicare statute, regulations, and applicable policies," and that its decision "is supported by substantial evidence in the applicable administrative record." (Doc. 35 at 2.)

The text of the applicable statute, regulations, and policies are not in dispute. As noted above, Medicare Part B generally covers, among other things, "medical and other health care

services." 42 U.S.C. § 1395k(a)(2)(B). "Medical and other health services" includes DME. *Id.* § 1395x(s)(6). The statutory definition of DME is a list of certain equipment that is included and certain equipment that is excluded. *Id.* § 1395x(n). DME is defined to include "blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations)." *Id.*

Because § 1395x(n) is not an exhaustive list of items that qualify as DME, the regulations fill in the gaps with the following test:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
>
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> (3) Is primarily and customarily used to serve a medical purpose.
>
> (4) Generally is not useful to an individual in the absence of an illness or injury.
>
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202. The heart of the issue presented in this case is whether Dr. Bloom's CGM meets condition (3): is it "primarily and customarily used to serve a medical purpose?" In approaching that question, the court refers to relevant guidance documents.

The Medicare Act provides for "national coverage determinations" (NCDs) and "local coverage determinations" (LCDs). 42 U.S.C. § 1395ff(f). NCDs are "determination[s] by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter" and LCDs are determinations by Medicare administrative contractors "respecting whether or not a particular item or service is covered on an intermediary- or carrier-

wide basis." *Id.* § 1395ff(f)(1)(B), (f)(2)(B); *see also id.* § 1395y(*l*)(6); 42 C.F.R. §§ 405.1060, 405.1062. NCDs are binding on the MAC. 42 C.F.R. § 405.1060(a)(4). LCDs are not binding on the MAC, but are entitled to "substantial deference" if applicable to a particular case. *Id.* § 405.1062(a).

The 2016 MAC decision discussed two relevant NCDs, one relevant LCD, and one relevant "policy article." (*See* AR1 at 8–10.) NCD 280.1 is a "Durable Medical Equipment Reference List," and it states that Medicare covers "Blood Glucose Monitors" if a beneficiary meets certain conditions, referencing NCD 40.2. (AR1 at 8.) In turn, NCD 40.2 states that "[b]lood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood." (*Id.*)[4] The MAC found that NCD 40.2 does not apply because it "does not specifically address CGMs, which do not measure glucose in the blood but rather in the interstitial fluid." (AR1 at 9.) In support of that conclusion, the MAC took notice of the supplier's website, which states that CGMs measure glucose levels in tissue fluid (not blood). (AR1 at 9 & n.4.)

The MAC turned to LCD L11530 and policy article A33614, both entitled "Glucose Monitors." (AR1 at 9.)[5] The LCD includes a list of codes, including codes for sensors, transmitters, and receivers (monitors) for use with CGM systems. But the LCD cautions that the

[4] The full text of NCD 280.1 and NCD 40.2 is published in the *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html. The text is also available online via the "Medicare Coverage Database," available at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx (search for document numbers "280.1" and "40.2").

[5] LCD L11530 and policy article A33614 are now "superseded" or "retired," but versions of each were in effect on the dates of service of the items that were the subject of the 2016 MAC decision. (*See* AR1 at 9; *see id* at 3 (sensors and transmitter at issue were furnished in March and June 2014).) The text of the obsolete LCD and policy article is available on the CMS Medicare Coverage Database Archive Site, https://localcoverage.cms.gov/mcd_archive/.

appearance of a code "does not necessarily indicate coverage." (AR1 at 10.) The LCD refers to a "related Policy Article," presumably A33614. (*Id.*) In turn, the policy article specifically states that CGMs "are considered precautionary and therefore non-covered under the DME benefit." (*Id.*)

The MAC observed that it was not bound by LCDs or policy articles like LCD L11530 or policy article A33614. (*See* AR1 at 9.) But the MAC stated that it was required to give "substantial deference" to LCDs if applicable in a given case. (*Id.* (citing 42 C.F.R. § 405.1062(a).) The MAC also stated that "[h]istorically we have also given substantial deference to policy articles." (*Id.*) The MAC reasoned that policy article A33614 "makes clear" that the CGM items at issue "do not meet the definition of DME because they are precautionary." (AR1 at 10.) According to the MAC:

> While the term "precautionary" is not a statutorily defined term, it refers to the requirement that DME must itself serve a medical purpose. Where the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, but not for a primary medical purpose.

(*Id.*) The MAC observed that Dr. Bloom still needs to monitor his blood glucose levels using a finger stick, that the CGM manufacturer's website indicates that blood glucose testing is required to calibrate the CGM at least once every 12 hours, and that a fingerstick is still required before therapy adjustment. (AR1 at 10–11.) The MAC concluded that Dr. Bloom's CGM "merely provides an added precaution and does not itself serve a primary medical purpose." (AR1 at 11.)

Like the MAC, the court begins by analyzing the relevant policy determinations. Dr. Bloom argues that the MAC's analysis of NCD 280.1 was erroneous because, in his view, "[c]overage of glucose monitors is specifically contemplated in NCD 280.1" and "[n]o exclusion is made for CGMs." (Doc. 34 at 20.) The court rejects that argument. It is undisputed that a CGM system measures glucose in the interstitial fluid. (Doc. 21 ¶ 75; Doc. 26 ¶ 75.) Interstitial

fluid is not blood. *See Stedman's Medical Dictionary* 341120 (2014) (interstitial fluid, or "tissue fluid," is "the fluid in spaces between the tissue cells, constituting about 16% of the weight of the body; closely similar in composition to lymph"). CGMs therefore do not directly measure blood glucose. Moreover, in light of NCD 280.1's explicit reference to NCD 40.2, the "blood glucose monitors" mentioned in NCD 280.1 cannot reasonably be understood to include any technology other than a blood glucose meter that reads test strips. The court finds no error in the MAC's determination that NCD 280.1 and NCD 40.2 do not apply.

The court concludes, however, that the MAC did err in relying on LCD L11530 and policy article A33614. Those documents state that CGMs are not DME because CGMs are "precautionary." The MAC and the Secretary interpret that term "precautionary" to refer to the requirement in 42 C.F.R. § 414.202 that DME must be "primarily and customarily used to serve a medical purpose." Whatever term is used, the analysis is the same: whether the equipment is "primarily and customarily used to serve a medical purpose."

Here, no evidence supports the MAC's conclusion that a CGM is not "primarily and customarily used to serve a medical purpose." No record evidence suggests that CGMs are used for any nonmedical purpose. The Secretary has not stated what nonmedical purpose a CGM might serve. The sole evidence upon which the MAC and the Secretary rely is evidence that Dr. Bloom continues to monitor his blood glucose levels using a finger stick, that the CGM system at issue must be calibrated daily using a fingerstick, and that a fingerstick is still required for therapy adjustment. That evidence does not support the MAC's decision.

As Dr. Bloom testified, even when using a CGM, "you still need to monitor your blood sugar and prick your finger," but a CGM "may help you spot patterns or trends easier." (AR1 at 385.) As the court understands it, the fingerstick/blood glucose meter technology is

accurate and effective, but only gives the user a reading for a single point in time. A CGM gives much more frequent readings, but needs to be calibrated and confirmed with fingersticks from time to time.

A fingerstick might be necessary for "therapy adjustment." But the evidence does not suggest that Dr. Bloom uses his CGM for therapy adjustment; he uses it to supply close to real-time information about his labile glucose levels. The CGM does not replace fingersticks, but it performs a function that fingersticks do not. And a technology's purpose is not altered just because it must be calibrated or confirmed by another technology. The primary and customary purpose of a mechanical clock is to tell time, and that purpose is the same regardless of the fact that the clock might occasionally need to be calibrated with reference to a more accurate clock.[6]

The MAC's decision erroneously suggests a distinction between "primary" medical equipment and secondary or "additional" equipment. (*See* AR1 at 10 ("Where the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, but not for a primary medical purpose.").) The requirement in 42 C.F.R. § 414.202 that the equipment be "primarily and customarily used to serve a medical purpose" has nothing to do with whether the equipment is the "primary" equipment used to serve that purpose. A beneficiary might need and use a wheelchair for mobility most of the time, and might also need and use a walker or cane some of the time. The walker or cane is still "primarily and customarily used to serve a medical purpose."

[6] Notably, at least some kinds of blood glucose monitors themselves—which are DME under 42 U.S.C. § 1395x(n)—must be calibrated by the user. *See* Shridhara Alva, Ph.D., *FreeStyle Lite—A Blood Glucose Meter that Requires No Coding*, J. Diabetes Sci. & Tech. 546, 547 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769754/pdf/dst-02-0546.pdf (noting that some technologies require the user to configure the meter to the strip lot).

As the MAC observed, the term "precautionary" is not defined in the Medicare Act. Nor does the term appear in the applicable regulations. Aside from policy article A33614, the term does appear in NCD 280.1 and in the *Medicare Benefit Policy Manual* (MBPM). The DME reference list in NCD 280.1 lists items of equipment and remarks on whether they are covered. "Regulated" portable oxygen systems are covered, but "preset" portable oxygen systems and units are not because they are "precautionary equipment; essentially not therapeutic in nature." Spare tanks of oxygen are not covered because they are a "convenience or precautionary supply." The term also appears in the MPBM, which lists equipment that, although it could have "some remote medically related use," is not primarily and customarily used to serve a medical purpose. The MBPM supplies examples of such nonmedical equipment, including air conditioners, humidifiers, physical fitness equipment, and "first-aid or precautionary-type equipment (such as preset portable oxygen units)." MBPM, Pub. No. 100-02, Ch. 15, § 110.1(B)(2), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

To the extent that the term "precautionary" is used in NCD 280.1 and in the MBPM to explain why preset portable oxygen units and spare oxygen tanks are not "primarily and customarily used to serve a medical purpose," the evidence in this case does not support the conclusion that Dr. Bloom uses his CGM as backup or emergency equipment. The evidence is that he uses it routinely to avoid hypoglycemia. As Dr. Pratley stated, it is an essential part of Dr. Bloom's diabetes management. For all of the above reasons, the MAC erred in relying on LCD L11530 and policy article A33614. Regardless of whether the MAC might have

erroneously given substantial deference to policy article A33614,[7] application of the correct legal standard can lead to only one conclusion: adopting the reasoning of policy article A33614 was error.[8]

Other courts addressing this issue have reached similar conclusions. The court in *Whitcomb v. Hargan* held that the Appeals Council erred when it denied coverage for a Medtronic MiniMed CGM used by a beneficiary with Type 1 diabetes and hypoglycemic unawareness, reasoning that the phrase "primarily and customarily used to serve a medical purpose" is clear on its face, and that the CGM at issue "indisputably satisfies" that requirement. No. 2:17-CV-14 (E.D. Wis. Oct. 26, 2017), ECF No. 19.[9] A recent decision from the District of Massachusetts suggests the same. *See Finigan v. Burwell*, 189 F. Supp. 3d 201, 207 n.6 (D. Mass. 2016) (Secretary's construction of the term "precautionary" was under-explained; diabetic beneficiary's blood-testing regime "seems irrelevant to whether her [continuous glucose monitoring system] is 'durable medical equipment'").

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[7] This was the topic at issue when the court denied the Secretary's motion for a sentence-six remand. (*See* Doc. 20.)

[8] As noted above, policy article A33614 has been superseded. A relatively recent CMS ruling has been issued to "articulate[] CMS policy concerning the classification of continuous glucose monitoring systems as durable medical equipment under Part B of the Medicare program." CMS Ruling No. 1682-R, at 1 (Jan. 12, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf. (A CMS ruling is a precedential final opinion, order, or statement of policy or interpretation—*see* 42 C.F.R. § 401.108.) That ruling purports to draw a distinction between "therapeutic" and "non-therapeutic" CGMs, but the ruling does not apply in this case. *See* CMS Ruling No. 1682-R, at 7 ("This Ruling applies to certain CGMs furnished on or after the effective date of the Ruling.").

[9] A copy of the *Whitcomb* decision appears in this court's record at Doc. 42-1.

III. Remaining Requirements for Coverage; Disposition

In addition to the requirement that equipment be "primarily and customarily used to serve a medical purpose," the regulations specify four other requirements for equipment to constitute DME. The equipment must be capable of withstanding repeated use, have an expected life of at least three years, be generally unuseful absent an illness or injury, and be appropriate for home use. *See* 42 C.F.R. § 414.202. In addition, there is a statutory exclusion from coverage for "any expenses incurred for items or services . . . [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

Because the MAC (and the ALJs below) concluded that Dr. Bloom's CGM was not "primarily and customarily used to serve a medical purpose," those decisionmakers did not address any of these remaining requirements for coverage. The Secretary says that he has not conceded or determined any of the remaining criteria for Medicare coverage—particularly the requirement that the item be "reasonable and necessary"—and that the disposition should be a remand for determination of those criteria rather than for payment of claims. (Doc. 44 at 3.) Dr. Bloom argues, among other things, that the record contains sufficient evidence to make these determinations here. (Doc. 45 at 2.)

The court is empowered to enter a judgment "affirming, modifying, or reversing the decision . . . with or without remanding the cause for a rehearing." 42 U.S.C. § 405(g). Reversal is appropriate in this case because of the error identified in the discussion above. For the reasons below, the court concludes that there is no basis for a remand to develop the record on the remaining regulatory factors for DME or on the "reasonable and necessary" inquiry. *See Butts v. Barnhart*, 388 F.3d 377, 385 (2d Cir. 2004) (remand for further development of evidence is

unnecessary where there is "no apparent basis to conclude that a more complete record might support the . . . decision" (quoting *Rosa v. Callahan*, 168 F.3d 72, 83 (2d Cir. 1999))); *Shaw v. Chater*, 221 F.3d 126, 135 (2d Cir. 2000) (remand unnecessary where record provided "overwhelming proof" on relevant issue).

The court briefly analyzes the relevant regulatory factors. The CGM system is capable of repeated use. The only "disposable" item in the system is the sensors. (*See* AR1 at 379.) Even though the sensors are disposable, they are supplies or accessories necessary for the effective use of the equipment. *See* MBPM, Pub. No. 100-02, Ch. 15, § 110.3 ("Payment may be made for supplies, e.g., oxygen, that are necessary for the effective use of durable medical equipment."). Dr. Bloom has been using his CGM system for years, easily satisfying the three-year expected life requirement. (*See* AR1 at 384.)[10] The record amply describes the usefulness of the CGM for individuals with brittle diabetes and hypoglycemic unawareness; there appears to be no use for a CGM other than to monitor glucose levels. The record similarly describes the CGM as a system appropriate for home use—indeed, the main benefit of the system is that it supplies data at all times: at home, while asleep, on airplanes, etc.

The record also establishes that the CGM is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). ALJs in other cases have explicitly made that finding with respect to Dr. Bloom's CGM system. (*See, e.g.*, AR1 at 204.) The record evidence also overwhelmingly proves that the CGM is reasonable and necessary for Dr. Bloom. His treating physicians have prescribed it to him and opined that it is both significantly beneficial and essential. Without a CGM, Dr. Bloom is at risk of serious injury or death as a result of his brittle

[10] ALJs who have rendered favorable decisions for Dr. Bloom's CGM in other cases have not suggested any failure to meet the three-year requirement. (*See, e.g.*, AR1 at 193–205.)

diabetes and hypoglycemic unawareness. There is no basis for a remand to develop the record on the remaining requirements for coverage, and the proper disposition is a remand with instructions to authorize coverage.

Conclusion

Dr. Bloom's Motion to Reverse (Doc. 34) and the Secretary's Motion to Affirm (Doc. 35) are each GRANTED IN PART and DENIED IN PART.

Dr. Bloom's Motion is DENIED and the Secretary's Motion is GRANTED with respect to the Medicare Appeals Council's decision dated November 13, 2015 (No. M-15-1505) and the Medicare Appeals Council's decision dated January 27, 2017 (No. M-16-10554). The court lacks jurisdiction to review those decisions, and Dr. Bloom's challenge to those decisions is DISMISSED.

Dr. Bloom's Motion is GRANTED and the Secretary's Motion is DENIED with respect to the Medicare Appeals Council's decision dated February 24, 2016 (No. M-15-4332). The 2016 decision is REVERSED and the action is REMANDED to the Secretary under sentence four of 42 U.S.C. § 405(g), with instructions to authorize coverage for the CGM items at issue.

Dated at Rutland, in the District of Vermont, this 29 day of January, 2018.

Geoffrey W. Crawford, Chief Judge
United States District Court